# IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TEXAS MARSHALL DIVISION

ALLERGAN, INC.,

Plaintiff,

v.

Civil Action No. 2:15-cv-1455

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., APOTEX, INC., APOTEX CORP., AKORN, INC., MYLAN PHARMACEUTICALS, INC., and MYLAN, INC.,

Defendants.

**JURY TRIAL DEMANDED** 

# **ALLERGAN, INC.'S COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Allergan, Inc. ("Allergan" or "Plaintiff"), for its Complaint against Defendants

Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively "Teva");

Apotex, Inc. and Apotex Corp. (collectively "Apotex"); Akorn, Inc. ("Akorn"); and Mylan

Pharmaceuticals, Inc. and Mylan, Inc. (collectively "Mylan"), by its attorneys, alleges as follows:

# **The Nature of the Action**

- 1. This is an action for infringement of United States Patent Nos. 8,629,111 ("the '111 Patent"), 8,633,162 ("the '162 Patent"), 8,642,556 ("the '556 Patent"), 8,648,048 ("the '048 Patent"), and 8,685,930 ("the '930 Patent") under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, relating to Allergan's treatment for chronic dry eye, Restasis®.
- 2. This is also an action under 35 U.S.C. §§ 2201-02 for a declaratory judgment of infringement of the '111, '556, and '930 Patents under 35 U.S.C. § 271 (a), (b), and (c), and for a

declaratory judgment of infringement of the '162 and '048 Patents under 35 U.S.C. § 271 (b) and (c).

# **The Parties**

- 3. Allergan is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 2525 Dupont Drive, Irvine, California 92612.
- 4. Allergan operates a facility in Waco, Texas where it manufactures and distributes numerous pharmaceutical products, including RESTASIS® (cyclosporine ophthalmic emulsion, 0.05%). Allergan coordinates the nationwide distribution of RESTASIS® from Texas. Allergan employs over 800 individuals in Texas, more than in any other state except California.
- 5. On information and belief, defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania, 19454-1090.
- 6. On information and belief, Teva USA is a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd.
- 7. On information and belief, Teva Pharmaceutical Industries Ltd. ("Teva Pharmaceutical") is a corporation organized and existing under the laws of Israel, with a place of business at 5 Basel St., Petach Tikva Israel, 49131.
- 8. On information and belief, Teva USA and Teva Pharmaceutical are agents of each other and/or work in active concert with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products.

- 9. On information and belief, Apotex, Inc. is a corporation organized and existing under the laws of Canada with its principal place of business located at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.
- 10. On information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326.
- 11. On information and belief, Apotex, Corp. is a wholly-owned subsidiary of Apotex Inc.
- 12. On information and belief, Apotex, Inc. and Apotex Corp. are agents of each other and/or work in active concert with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products.
- 13. On information and belief, Akorn is a corporation organized and existing under the laws of the State of Louisiana with its principal place of business located at 1925 West Field Court, Suite 300, Lake Forest, Illinois 60045, and a registered agent located at 211 East 7th Street, Suite 620, Austin, Texas 78701-3218.
- 14. On information and belief, Mylan Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of West Virginia with its principal place of business located at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505, and a registered agent located at 211 East 7th Street, Suite 620, Austin, Texas 78701-3218.
- 15. On information and belief, Mylan, Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal place of business located at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

- 16. On information and belief, Mylan Pharmaceuticals, Inc. is a wholly-owned subsidiary of Mylan, Inc.
- 17. On information and belief, Mylan Pharmaceuticals, Inc. and Mylan, Inc. are agents of each other and/or work in active concert with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products.

### **Venue and Jurisdiction**

- 18. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1, *et seq.* This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338.
- 19. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, induced, contributed to, and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs in Texas. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such personal jurisdiction is challenged.

#### A. Personal Jurisdiction over Teva USA and Teva Pharmaceutical

- 20. This Court has personal jurisdiction over Teva USA and Teva Pharmaceutical by virtue of their systematic and continuous contact with this jurisdiction, as alleged herein, and because of the injury to Allergan in this forum arising from Teva's ANDA filing and the causes of action Allergan alleges. *See Allergan, Inc. v. Actavis, Inc. et al.*, No 2:14-cv-0063, 2014 WL 7336692, at \*5-8 (E.D. Tex. December 23, 2014).
- 21. On information and belief, Teva submitted ANDA No. 203880 under section 505(j) of the FDCA, 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial

manufacture, use, importation, sale, or offer for sale of Cyclosporine Ophthalmic Emulsion, 0.05%, a generic version of Allergan's RESTASIS® product.

- 22. On information and belief, Teva USA and Teva Pharmaceutical are agents of each other and/or work in active concert with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products, including the generic Cyclosporine Ophthalmic Emulsion, 0.05% described in ANDA No. 203880.
- 23. On information and belief, Teva USA is a licensed drug distributor of prescription drugs sold in the State of Texas.
- 24. On information and belief, Teva USA is actively registered with the Texas Secretary of State to conduct business in Texas.
- 25. On information and belief, various Teva drug products appear in the Texas prescription drug formulary.
- 26. On information and belief, Teva Pharmaceutical markets and sells numerous generic drugs, manufactured and supplied by Teva USA. On information and belief, since 2014 Teva Pharmaceutical has sold nearly \$1.8 billion worth of Teva USA's products in Texas, over \$330 million of which were sold in this judicial district.
- 27. Teva has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction. *Pozen, Inc. v. Teva Pharmaceuticals USA, Inc.*, 6:08-cv-437, D.I. 83 at 2 (E.D. Tex.); *Aventis Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc. et al.*, 2:06-cv-469, D.I. 27 at 2 (E.D. Tex.). Teva has also availed itself to this judicial district through the assertion of counterclaims. *Pozen, Inc. v. Teva Pharmaceuticals USA, Inc.*, 6:09-cv-182, D.I. 11 at 2 (E.D. Tex.).

- 28. On information and belief, Teva knows and intends that its proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will be distributed and sold in Texas.
- 29. On information and belief, Teva knows and intends that sales of its proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will displace sales of Allergan's RESTASIS® product causing injury to Allergan in Texas.
- 30. On information and belief, Teva intends to take advantage of its established channels of distribution in Texas for the sale of its proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880. On information and belief, Teva arranged these distribution channels to take advantage of the second largest market for prescription drugs in the United States.
  - 31. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).
  - B. Personal Jurisdiction over Apotex, Inc. and Apotex Corp.
- 32. This Court has personal jurisdiction over Apotex, Inc. and Apotex Corp. by virtue of their systematic and continuous contact with this jurisdiction, as alleged herein, and because of the injury to Allergan in this forum arising from Apotex's ANDA filing and the causes of action Allergan raises here, as alleged herein. *See Allergan, Inc. v. Actavis, Inc. et al.*, No 2:14-cv-0063, 2014 WL 7336692, at \*5-8 (E.D. Tex. December 23, 2014).
- 33. On information and belief, Apotex, Inc. submitted ANDA No. 207606 under section 505(j) of the FDCA, 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, importation, sale, or offer for sale of Cyclosporine Ophthalmic Emulsion, 0.05%, a generic version of Allergan's RESTASIS® product.

- 34. On information and belief, Apotex, Inc. and Apotex Corp. are agents of each other and/or work in active concert with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products, including the generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606.
- 35. On information and belief, Apotex Corp. is a licensed drug distributor of prescription drugs sold in the State of Texas.
- 36. On information and belief, Apotex, Inc. is actively registered with the Texas Secretary of State to conduct business in Texas.
- 37. On information and belief, Apotex, Inc.'s drug products are listed on the Texas prescription drug formulary.
- 38. On information and belief, Apotex Corp. markets and sells numerous generic drugs, manufactured and supplied by Apotex, Inc. On information and belief, since 2014 Apotex Corp. has sold nearly \$420 million worth of Apotex, Inc.'s products in Texas, over \$98 million of which were sold in this judicial district.
- 39. Apotex, Inc. and Apotex Corp. have previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction. *Allergan, Inc. v. Sandoz, Inc. et al.*, 2:12-cv-207, D.I. 28 at 4 (E.D. Tex.); *Allergan, Inc. v. Apotex, Inc. and Apotex Corp.*, 2:12-cv-530, D.I. 64 at 4 (E.D. Tex.). Apotex, Inc. and Apotex Corp. have also availed themselves to this judicial district through the assertion of counterclaims. *Allergan Sales, LLC v. Apotex, Inc. and Apotex Corp.*, 2:12-cv-178, D.I. 17 at 4 (E.D. Tex.); *Allergan, Inc. v. Apotex, Inc. and Apotex Corp.*, 2:10-cv-200, D.I. 11 at 2 (E.D. Tex.).

- 40. Apotex Inc. and Apotex Corp. have also previously availed themselves to this judicial district by filing a lawsuit in this judicial district. *Apotex, Inc. et al. v. Lupin, Ltd. and Lupin Pharmaceuticals, Inc.*, 2:15-cv-599, D.I. 1 (E.D. Tex.).
- 41. On information and belief, Apotex, Inc. and Apotex Corp. know and intend that its proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will be distributed and sold in Texas.
- 42. On information and belief, Apotex knows and intends that sales of its proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will displace sales of Allergan's RESTASIS® product causing injury to Allergan in Texas.
- 43. On information and belief, Apotex intends to take advantage of its established channels of distribution in Texas for the sale of its proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606. On information and belief, Apotex arranged these distribution channels to take advantage of the Texas market, the second largest market for prescription drugs in the United States.
  - 44. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

# C. Personal Jurisdiction over Akorn

- 45. This Court has personal jurisdiction over Akorn by virtue of its systematic and continuous contact with this jurisdiction, as alleged herein, and because of the injury to Allergan in this forum arising from Akorn's ANDA filing and the causes of action Allergan alleges. *See Allergan, Inc. v. Actavis, Inc. et al.*, No 2:14-cv-0063, 2014 WL 7336692, at \*5-8 (E.D. Tex. December 23, 2014).
- 46. On information and belief, Akorn submitted ANDA No. 204561 under section 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j) ("FDCA"), seeking

approval from the United States Food and Drug Administration ("FDA") to engage in the commercial manufacture, use, importation, sale, or offer for sale of Cyclosporine Ophthalmic Emulsion, 0.05%, a generic version of Allergan's RESTASIS® product.

- 47. On information and belief, Akorn is in the business of developing, manufacturing, distributing, and selling generic drug products throughout the United States, including for distribution and sale in this judicial district.
- 48. On information and belief, Akorn is a licensed drug distributor of prescription drugs sold in the State of Texas.
- 49. On information and belief, Akorn is actively registered with the Texas Secretary of State to conduct business in Texas.
- 50. On information and belief, since 2014, Akorn has sold nearly \$50 million worth of Akorn's products in Texas, over \$5 million of which were sold in this judicial district.
- 51. Akorn has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction. *Allergan, Inc. v. Lupin Ltd. et al.*, 2:11-cv-00530, D.I. 61 at 3 (E.D. Tex.).
- 52. On information and belief, Akorn has a registered agent in Texas located at 211 East 7th Street, Suite 620, Austin, Texas 78701-3218.
- 53. On information and belief, various Akorn drug products appear on the Formulary Index of the Texas CHIP/Medicaid Vendor Drug Program, which provides services for over 4,000 Texas pharmacies.
- 54. On information and belief, Akorn has entered into arrangements with Texas entities to have its products appear on the formulary list of Blue Cross Blue Shield Texas, a major managed care and health plan.

- 55. On information and belief, Akorn has authorized numerous customers in Texas to distribute Akorn generic products, including AmerisourceBergen Drug Corp., Cardinal Health, Inc., McKesson Corp., and Walgreen Co.
- 56. On information and belief, Akorn knows and intends that its proposed Cyclosporine Ophthalmic Emulsion, 0.05% described in ANDA No. 204561 will be distributed and sold in Texas.
- 57. On information and belief, Akorn knows and intends that sales of its proposed Cyclosporine Ophthalmic Emulsion, 0.05% % described in ANDA No. 204561 will displace sales of Allergan's RESTASIS® product causing injury to Allergan in Texas.
- 58. On information and belief, Akorn intends to take advantage of its established channels of distribution in Texas for the sale of its proposed Cyclosporine Ophthalmic Emulsion, 0.05% described in ANDA No. 204561. On information and belief, Akorn arranged these distribution channels to take advantage of the Texas market, the second largest market for prescription drugs in the United States.
  - 59. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).
  - D. Personal Jurisdiction over Mylan Pharmaceuticals and Mylan, Inc.
- 60. This Court has personal jurisdiction over Mylan Pharmaceuticals, Inc. ("Mylan Pharmaceuticals") and Mylan, Inc. by virtue of their systematic and continuous contact with this jurisdiction, as alleged herein, and because of the injury to Allergan in this forum arising from Mylan's ANDA filing and the causes of action Allergan alleges. *See Allergan, Inc. v. Actavis, Inc. et al.*, No 2:14-cv-0063, 2014 WL 7336692, at \*5-8 (E.D. Tex. December 23, 2014).
- 61. On information and belief, Mylan submitted ANDA No. 205894 under section 505(j) of the FDCA, 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial

manufacture, use, importation, sale, or offer for sale of Cyclosporine Ophthalmic Emulsion, 0.05%, a generic version of Allergan's RESTASIS® product.

- 62. On information and belief, Mylan Pharmaceuticals and Mylan, Inc. are agents of each other and/or work in active concert with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products, including the generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894.
- 63. On information and belief, Mylan Pharmaceuticals is a licensed drug distributor of prescription drugs sold in the State of Texas.
- 64. On information and belief, Mylan Pharmaceuticals is actively registered with the Texas Secretary of State to conduct business in Texas.
- 65. On information and belief, various Mylan Pharmaceuticals drug products appear in the Texas prescription drug formulary.
- 66. On information and belief, Mylan, Inc. markets and sells numerous generic drugs, manufactured and supplied by Mylan Pharmaceuticals. On information and belief, since 2014 Mylan, Inc. has sold over \$1.3 billion worth of Mylan Pharmaceuticals' products in Texas, over \$460 million of which were sold in this judicial district.
- 67. On information and belief, Mylan Pharmaceuticals has a registered agent in Texas located at 211 East 7th Street, Suite 620, Austin, Texas 78701-3218.
- 68. On information and belief, Mylan, Inc. has further availed itself to the laws of Texas through its subsidiary, Mylan Institutional, Inc., which is located at 12720 Dairy Ashford Road, Sugar Land, Texas 77478.

- 69. On information and belief, Mylan knows and intends that its proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will be distributed and sold in Texas.
- 70. On information and belief, Mylan knows and intends that sales of its proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will displace sales of Allergan's RESTASIS® product causing injury to Allergan in Texas.
- 71. On information and belief, Mylan intends to take advantage of its established channels of distribution in Texas for the sale of its proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894. On information and belief, Mylan arranged these distribution channels to take advantage of the Texas market, the second largest market for prescription drugs in the United States.
  - 72. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

# **Factual Background**

# A. Patents-In-Suit

- 1. U.S. Patent No. 8,629,111
- 73. On January 14, 2014, the '111 Patent, titled "Methods of Providing Therapeutic Effects Using Cyclosporin Components," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") to inventors Andrew Acheampong, Diane D. Tang-Liu, James N. Chang, and David F. Power. A true and correct copy of the '111 Patent is attached to this complaint as Exhibit 1.
  - 74. Allergan, as assignee, owns the entire right, title, and interest in the '111 Patent.
- 75. Allergan is the holder of approved New Drug Application ("NDA") No. 50-790 for Cyclosporine Ophthalmic Emulsion, 0.05%, sold under the RESTASIS® trademark.

- 76. The '111 Patent is listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for RESTASIS®.
- 77. RESTASIS® and/or methods of using RESTASIS® are covered by at least one claim of the '111 Patent.

### 2. U.S. Patent No. 8,633,162

- 78. On January 21, 2014, the '162 Patent, titled "Methods of Providing Therapeutic Effects Using Cyclosporin Components," was duly and legally issued by the USPTO to inventors Andrew Acheampong, Diane D. Tang-Liu, James N. Chang, and David F. Power. A true and correct copy of the '162 Patent is attached to this complaint as Exhibit 2.
  - 79. Allergan, as assignee, owns the entire right, title, and interest in the '162 Patent.
- 80. Allergan is the holder of approved New Drug Application ("NDA") No. 50-790 for Cyclosporine Ophthalmic Emulsion, 0.05%, sold under the RESTASIS® trademark.
  - 81. The '162 Patent is listed in the Orange Book for RESTASIS®.
- 82. RESTASIS® and/or methods of using RESTASIS® are covered by at least one claim of the '162 Patent.

# 3. U.S. Patent No. 8,642,556

- 83. On February 4, 2014, the '556 Patent, titled "Methods of Providing Therapeutic Effects Using Cyclosporin Components," was duly and legally issued by the USPTO to inventors Andrew Acheampong, Diane D. Tang-Liu, James N. Chang, and David F. Power. A true and correct copy of the '556 Patent is attached to this complaint as Exhibit 3.
  - 84. Allergan, as assignee, owns the entire right, title, and interest in the '556 Patent.
- 85. Allergan is the holder of approved New Drug Application ("NDA") No. 50-790 for Cyclosporine Ophthalmic Emulsion, 0.05%, sold under the RESTASIS® trademark.

- 86. The '556 Patent is listed in the Orange Book for RESTASIS®.
- 87. RESTASIS® and/or methods of using RESTASIS® are covered by at least one claim of the '556 Patent.

#### 4. U.S. Patent No. 8,648,048

- 88. On February 11, 2014, the '048 Patent, titled "Methods of Providing Therapeutic Effects Using Cyclosporin Components," was duly and legally issued by the USPTO to inventors Andrew Acheampong, Diane D. Tang-Liu, James N. Chang, and David F. Power. A true and correct copy of the '048 Patent is attached to this complaint as Exhibit 4.
  - 89. Allergan, as assignee, owns the entire right, title, and interest in the '048 Patent.
- 90. Allergan is the holder of approved New Drug Application ("NDA") No. 50-790 for Cyclosporine Ophthalmic Emulsion, 0.05%, sold under the RESTASIS® trademark.
  - 91. The '048 Patent is listed in the Orange Book for RESTASIS®.
- 92. RESTASIS® and/or methods of using RESTASIS® are covered by at least one claim of the '048 Patent.

# 5. U.S. Patent No. 8,685,930

- 93. On April 1, 2014, the '930 Patent, titled "Methods of Providing Therapeutic Effects Using Cyclosporin Components," was duly and legally issued by the USPTO to inventors Andrew Acheampong, Diane D. Tang-Liu, James N. Chang, and David F. Power. A true and correct copy of the '930 Patent is attached to this complaint as Exhibit 5.
  - 94. Allergan, as assignee, owns the entire right, title, and interest in the '930 Patent.
- 95. Allergan is the holder of approved New Drug Application ("NDA") No. 50-790 for Cyclosporine Ophthalmic Emulsion, 0.05%, sold under the RESTASIS® trademark.
  - 96. The '930 Patent is listed in the Orange Book for RESTASIS®.

97. RESTASIS® and/or methods of using RESTASIS® are covered by at least one claim of the '930 Patent.

# B. Acts Giving Rise to This Action

#### 1. Acts Giving Rise to this Action Against Teva

- 98. On information and belief, Teva submitted ANDA No. 203880 to the FDA under section 505(j) of the FDCA, seeking FDA approval to engage in the commercial manufacture, use, importation, sale, or offer for sale of Cyclosporine Ophthalmic Emulsion, 0.05%, a generic version of Allergan's RESTASIS® product.
- 99. On information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the FDCA, Teva included with its ANDA No. 203880 a Paragraph IV certification alleging that the claims of patents listed in the Orange Book as covering RESTASIS® are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Teva's Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880. Plaintiff received written notification of ANDA No. 203880 and its § 505(j)(2)(A)(vii)(IV) allegations with respect to the '111, '162, '556, '048, and '930 patents on or about July 23, 2015.
- 100. On information and belief, the FDA has not yet approved Teva's ANDA No. 203880.
- 101. On information and belief, Teva has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import a generic version of Allergan's RESTASIS® product before expiration of the patents-in-suit.
- 102. On information and belief, Teva continues to seek approval of ANDA No. 203880 from the FDA and intends to continue in the commercial manufacture, marketing, and sale of its proposed generic version of Allergan's RESTASIS® product.

103. On information and belief, following FDA approval of its ANDA No. 203880, Teva will sell the approved generic version of Allergan's RESTASIS® product throughout the United States, including in Texas and this judicial district.

#### 2. Acts Giving Rise to this Action Against Apotex

- 104. On information and belief, Apotex submitted ANDA No. 207606 to the FDA under section 505(j) of the FDCA, seeking FDA approval to engage in the commercial manufacture, use, importation, sale, or offer for sale of Cyclosporine Ophthalmic Emulsion, 0.05%, a generic version of Allergan's RESTASIS® product.
- 105. On information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the FDCA, Apotex included with its ANDA No. 207606 a Paragraph IV certification alleging that the claims of patents listed in the Orange Book as covering RESTASIS® are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Apotex's Cyclosporine Ophthalmic Emulsion, 0.05% product. Plaintiff received written notification of ANDA No. 207606 and its § 505(j)(2)(A)(vii)(IV) allegations with respect to the '111, '162, '556, '048, and '930 patents on or about July 24, 2015.
- 106. On information and belief, the FDA has not yet approved Apotex's ANDA No. 207606.
- 107. On information and belief, Apotex has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import a generic version of Allergan's RESTASIS® product before expiration of the patents-in-suit.
- 108. On information and belief, Apotex continues to seek approval of ANDA No. 207606 from the FDA and intends to continue in the commercial manufacture, marketing, and

sale of a generic version of Allergan's RESTASIS® product before expiration of the patents-insuit.

109. On information and belief, following FDA approval of its ANDA No. 207606,

Apotex will sell the approved generic version of Allergan's RESTASIS® product throughout the

United States, including in Texas and this judicial district.

#### 3. Acts Giving Rise to this Action Against Akorn

- 110. On information and belief, Akorn submitted ANDA No. 204561 to the FDA under section 505(j) of the FDCA, seeking FDA approval to engage in the commercial manufacture, use, importation, sale, or offer for sale of Cyclosporine Ophthalmic Emulsion, 0.05%, a generic version of Allergan's RESTASIS® product.
- 111. On information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the FDCA, Akorn included with its ANDA No. 204561 a Paragraph IV certification alleging that the claims of patents listed in the Orange Book as covering RESTASIS® are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Akorn's Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561. Plaintiff received written notification of ANDA No. 204561 and its § 505(j)(2)(A)(vii)(IV) allegations with respect to the '111, '162, '556, '048, and '930 patents on or about July 13, 2015.
- 112. On information and belief, the FDA has not yet approved Akorn's ANDA No. 204561.
- 113. On information and belief, Akorn has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import a generic version of Allergan's RESTASIS® product before expiration of the patents-in-suit.

- 114. On information and belief, Akorn continues to seek approval of ANDA No.

  204561 from the FDA and intends to continue in the commercial manufacture, marketing, and sale of its generic version of Allergan's RESTASIS® product before expiration of the patents-insuit.
- 115. On information and belief, following FDA approval of its ANDA No. 204561, Akorn will sell the approved generic version of Allergan's RESTASIS® product throughout the United States, including in Texas and this judicial district.

#### 4. Acts Giving Rise to this Action Against Mylan

- 116. On information and belief, Mylan submitted ANDA No. 205894 to the FDA under section 505(j) of the FDCA, seeking FDA approval to engage in the commercial manufacture, use, importation, sale, or offer for sale of Cyclosporine Ophthalmic Emulsion, 0.05%, a generic version of Allergan's RESTASIS® product.
- 117. On information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the FDCA, Mylan included with its ANDA No. 205894 a Paragraph IV certification alleging that the claims of patents listed in the Orange Book as covering RESTASIS® are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Mylan's Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894. Plaintiff received written notification of ANDA No. 205894 and its § 505(j)(2)(A)(vii)(IV) allegations with respect to the '111, '162, '556, '048, and '930 patents on or about July 21, 2015.
- 118. On information and belief, the FDA has not yet approved Mylan's ANDA No. 205894.

- 119. On information and belief, Mylan has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import a generic version of Allergan's RESTASIS® product before expiration of the patents-in-suit.
- 120. On information and belief, Mylan continues to seek approval of ANDA No.

  205894 from the FDA and intends to continue in the commercial manufacture, marketing, and sale of its proposed generic version of Allergan's RESTASIS® product.
- 121. On information and belief, following FDA approval of its ANDA No. 205894, Mylan will sell the approved generic version of Allergan's RESTASIS® product throughout the United States, including in Texas and this judicial district.

#### **Count I**

(Infringement of the '111 Patent Under 35 U.S.C. § 271(e)(2) by Teva's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 122. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 123. Teva submitted ANDA No. 203880 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Teva has committed an act of infringement of the '111 Patent under 35 U.S.C. § 271(e)(2)(A).
- 124. The commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will constitute an act of direct infringement of the '111 Patent.
- 125. On information and belief, Teva became aware of the '111 Patent no later than the date on which that patent was listed in the Orange Book.

- 126. On information and belief, Teva knows or should know that the commercial offer for sale and sale of Teva's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880, will constitute an act of induced infringement and will contribute to actual infringement of the '111 Patent.
- 127. On information and belief, Teva knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will be especially made for or especially adapted for an infringement of the '111 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will actively contribute to the actual infringement of the '111 Patent.
- 128. The commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

# Count II (Declaratory Judgment of Infringement of the '111 Patent Under 35 U.S.C. § 271(a) by Teva)

- 129. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 130. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 131. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

- 132. The commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will constitute an act of direct infringement of one or more claims of the '111 Patent.
- 133. On information and belief, Teva will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 immediately and imminently upon approval of ANDA No. 203880.
  - 134. The foregoing actions by Teva will constitute infringement of the '111 Patent.
  - 135. Teva will commit those acts of infringement without license or authorization.
- 136. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 by Teva will infringe the '111 Patent.
- 137. Unless Teva is enjoined from infringing the '111 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

# **Count III**

(Declaratory Judgment of Infringement of the '111 Patent Under 35 U.S.C. § 271(b) and (c) by Teva's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 138. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 139. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

- 140. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
  - 141. Teva has actual knowledge of the '111 Patent.
- 142. On information and belief, Teva became aware of the '111 Patent no later than the date on which that patent was listed in the Orange Book.
- 143. On information and belief, Teva has acted with full knowledge of the '111 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '111 Patent.
- 144. The commercial manufacture, use, sale, offer for sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will induce the actual infringement of the '111 Patent.
- 145. On information and belief, Teva knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will actively induce the actual infringement of the '111 Patent.
- 146. On information and belief, Teva will encourage another's infringement of the '111 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880, which is covered by certain claims of the '111 Patent.
- 147. Teva's acts of infringement will be done with knowledge of the '111 Patent and with the intent to encourage infringement.

- 148. The foregoing actions by Teva will constitute active inducement of infringement of the '111 Patent.
- 149. On information and belief, Teva knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will be especially made or especially adapted for use in an infringement of the '111 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 150. The commercial manufacture, use, sale, offer for sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will contribute to the actual infringement of the '111 Patent.
- 151. On information and belief, Teva knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% described in ANDA No. 203880 will contribute to the actual infringement of the '111 Patent.
- 152. The foregoing actions by Teva will constitute contributory infringement of the '111 Patent.
- 153. On information and belief, Teva intends to, and will, actively induce and contribute to the infringement of the '111 Patent when ANDA No. 203880 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 154. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 by Teva will induce and/or contribute to the infringement of the '111 Patent.
- 155. The commercial manufacture, use, offer for sale, sale and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in

ANDA No. 203880, which will actively induce and/or contribute to infringement of the '111 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.

- 156. Unless Teva is enjoined from actively inducing and contributing to the infringement of the '111 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 157. On information and belief, despite having actual notice of the '111 Patent, Teva continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '111 Patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

### <u>Count IV</u> : 35 U.S.C. § 271(e)(2) by Apotex

(Infringement of the '111 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 158. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 159. Apotex submitted ANDA No. 207606 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Apotex has committed an act of infringement of the '111 Patent under 35 U.S.C. § 271(e)(2)(A).
- 160. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will constitute an act of direct infringement of the '111 Patent.
- 161. On information and belief, Apotex became aware of the '111 Patent no later than the date on which that patent was listed in the Orange Book.

- 162. On information and belief, Apotex knows or should know that the commercial offer for sale and sale of Apotex's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606, will constitute an act of induced infringement and will contribute to actual infringement of the '111 Patent.
- 163. On information and belief, Apotex knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will be especially made for or especially adapted for an infringement of the '111 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will actively contribute to the actual infringement of the '111 Patent.
- 164. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

# (Declaratory Judgment of Infringement of the '111 Patent Under 35 U.S.C. § 271(a) by Apotex)

- 165. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 166. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 167. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

- 168. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will constitute an act of direct infringement of one or more claims of the '111 Patent.
- 169. On information and belief, Apotex will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 immediately and imminently upon approval of ANDA No. 207606.
  - 170. The foregoing actions by Apotex will constitute infringement of the '111 Patent.
  - 171. Apotex will commit those acts of infringement without license or authorization.
- 172. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 by Apotex will infringe the '111 Patent.
- 173. Unless Apotex is enjoined from infringing the '111 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

# Count VI

- (Declaratory Judgment of Infringement of the '111 Patent Under 35 U.S.C. § 271(b) and (c) by Apotex's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)
  - 174. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 175. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

- 176. There is an actual case or controversy such that the Court may entertain

  Allergan's request for declaratory relief consistent with Article III of the United States

  Constitution, and that actual case or controversy requires a declaration of rights by this Court.
  - 177. Apotex has actual knowledge of the '111 Patent.
- 178. On information and belief, Apotex became aware of the '111 Patent no later than the date on which that patent was listed in the Orange Book.
- 179. On information and belief, Apotex has acted with full knowledge of the '111 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '111 Patent.
- 180. The commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will induce the actual infringement of the '111 Patent.
- 181. On information and belief, Apotex knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will actively induce the actual infringement of the '111 Patent.
- 182. On information and belief, Apotex will encourage another's infringement of the '111 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606, which is covered by certain claims of the '111 Patent.
- 183. Apotex's acts of infringement will be done with knowledge of the '111 Patent and with the intent to encourage infringement.

- 184. The foregoing actions by Apotex will constitute active inducement of infringement of the '111 Patent.
- 185. On information and belief, Apotex knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will be especially made or especially adapted for use in an infringement of the '111 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 186. The commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will contribute to the actual infringement of the '111 Patent.
- 187. On information and belief, Apotex knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% will contribute to the actual infringement of the '111 Patent.
- 188. The foregoing actions by Apotex will constitute contributory infringement of the '111 Patent.
- 189. On information and belief, Apotex intends to, and will, actively induce and contribute to the infringement of the '111 Patent when ANDA No. 207606 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 190. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 by Apotex will induce and/or contribute to the infringement of the '111 Patent.
- 191. The commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in

ANDA No. 207606, which will actively induce and/or contribute to infringement of the '111 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.

- 192. Unless Apotex is enjoined from actively inducing and contributing to the infringement of the '111 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 193. On information and belief, despite having actual notice of the '111 Patent, Apotex continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '111 Patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

#### **Count VII**

# (Infringement of the '111 Patent Under 35 U.S.C. § 271(e)(2) by Akorn's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 194. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 195. Akorn submitted ANDA No. 204561 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Akorn has committed an act of infringement of the '111 Patent under 35 U.S.C. § 271(e)(2)(A).
- 196. The commercial manufacture, use, offer for sale, sale, and/or importation of Akorn's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will constitute an act of direct infringement of the '111 Patent.
- 197. On information and belief, Akorn became aware of the '111 Patent no later than the date on which that patent was listed in the Orange Book.

- 198. On information and belief, Akorn knows or should know that the commercial offer for sale and sale of Akorn's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561, will constitute an act of induced infringement and will contribute to actual infringement of the '111 Patent.
- 199. On information and belief, Akorn knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will be especially made for or especially adapted for an infringement of the '111 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will actively contribute to the actual infringement of the '111 Patent.
- 200. The commercial manufacture, use, offer for sale, sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

#### **Count VIII**

# (Declaratory Judgment of Infringement of the '111 Patent Under 35 U.S.C. § 271(a) by Akorn)

- 201. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 202. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 203. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

- 204. The commercial manufacture, use, offer for sale, sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will constitute an act of direct infringement of one or more claims of the '111 Patent.
- 205. On information and belief, Akorn will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 immediately and imminently upon approval of ANDA No. 204561.
  - 206. The foregoing actions by Akorn will constitute infringement of the '111 Patent.
  - 207. Akorn will commit those acts of infringement without license or authorization.
- 208. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 by Akorn will infringe the '111 Patent.
- 209. Unless Akorn is enjoined from infringing the '111 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

# **Count IX**

- (Declaratory Judgment of Infringement of the '111 Patent Under 35 U.S.C. § 271(b) and (c) by Akorn's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)
  - 210. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 211. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

- 212. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
  - 213. Akorn has actual knowledge of the '111 Patent.
- 214. On information and belief, Akorn became aware of the '111 Patent no later than the date on which that patent was listed in the Orange Book.
- 215. On information and belief, Akorn has acted with full knowledge of the '111 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '111 Patent.
- 216. The commercial manufacture, use, sale, offer for sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will induce the actual infringement of the '111 Patent.
- 217. On information and belief, Akorn knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will actively induce the actual infringement of the '111 Patent.
- 218. On information and belief, Akorn will encourage another's infringement of the '111 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561, which is covered by certain claims of the '111 Patent.
- 219. Akorn's acts of infringement will be done with knowledge of the '111 Patent and with the intent to encourage infringement.

- 220. The foregoing actions by Akorn will constitute active inducement of infringement of the '111 Patent.
- 221. On information and belief, Akorn knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will be especially made or especially adapted for use in an infringement of the '111 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 222. The commercial manufacture, use, sale, offer for sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will contribute to the actual infringement of the '111 Patent.
- 223. On information and belief, Akorn knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will contribute to the actual infringement of the '111 Patent.
- 224. The foregoing actions by Akorn will constitute contributory infringement of the '111 Patent.
- 225. On information and belief, Akorn intends to, and will, actively induce and contribute to the infringement of the '111 Patent when ANDA No. 204561 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 226. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 by Akorn will induce and/or contribute to the infringement of the '111 Patent.

- 227. The commercial manufacture, use, offer for sale, sale and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561, which will actively induce and/or contribute to infringement of the '111 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 228. Unless Akorn is enjoined from actively inducing and contributing to the infringement of the '111 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 229. On information and belief, despite having actual notice of the '111 Patent, Akorn continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '111 Patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

#### Count X

# (Infringement of the '111 Patent Under 35 U.S.C. § 271(e)(2) by Mylan's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 230. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 231. Mylan submitted ANDA No. 205894 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Mylan has committed an act of infringement of the '111 Patent under 35 U.S.C. § 271(e)(2)(A).
- 232. The commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will constitute an act of direct infringement of the '111 Patent.

- 233. On information and belief, Mylan became aware of the '111 Patent no later than the date on which that patent was listed in the Orange Book.
- 234. On information and belief, Mylan knows or should know that the commercial offer for sale and sale of Mylan's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894, will constitute an act of induced infringement and will contribute to actual infringement of the '111 Patent.
- 235. On information and belief, Mylan knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will be especially made for or especially adapted for an infringement of the '111 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will actively contribute to the actual infringement of the '111 Patent.
- 236. The commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

# Count XI

# (Declaratory Judgment of Infringement of the '111 Patent Under 35 U.S.C. § 271(a) by Mylan)

- 237. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 238. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

- 239. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
- 240. The commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will constitute an act of direct infringement of one or more claims of the '111 Patent.
- 241. On information and belief, Mylan will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 immediately and imminently upon approval of ANDA No. 205894.
  - 242. The foregoing actions by Mylan will constitute infringement of the '111 Patent.
  - 243. Mylan will commit those acts of infringement without license or authorization.
- 244. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 by Mylan will infringe the '111 Patent.
- 245. Unless Mylan is enjoined from infringing the '111 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

#### **Count XII**

(Declaratory Judgment of Infringement of the '111 Patent Under 35 U.S.C. § 271(b) and (c) by Mylan's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

246. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

- 247. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 248. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
  - 249. Mylan has actual knowledge of the '111 Patent.
- 250. On information and belief, Mylan became aware of the '111 Patent no later than the date on which that patent was listed in the Orange Book.
- 251. On information and belief, Mylan has acted with full knowledge of the '111 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '111 Patent.
- 252. The commercial manufacture, use, sale, offer for sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will induce the actual infringement of the '111 Patent.
- 253. On information and belief, Mylan knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will actively induce the actual infringement of the '111 Patent.
- 254. On information and belief, Mylan will encourage another's infringement of the '111 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894, which is covered by certain claims of the '111 Patent.

- 255. Mylan's acts of infringement will be done with knowledge of the '111 Patent and with the intent to encourage infringement.
- 256. The foregoing actions by Mylan will constitute active inducement of infringement of the '111 Patent.
- 257. On information and belief, Mylan knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will be especially made or especially adapted for use in an infringement of the '111 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 258. The commercial manufacture, use, sale, offer for sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will contribute to the actual infringement of the '111 Patent.
- 259. On information and belief, Mylan knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will contribute to the actual infringement of the '111 Patent.
- 260. The foregoing actions by Mylan will constitute contributory infringement of the '111 Patent.
- 261. On information and belief, Mylan intends to, and will, actively induce and contribute to the infringement of the '111 Patent when ANDA No. 205894 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 262. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed generic

Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 by Mylan will induce and/or contribute to the infringement of the '111 Patent.

- 263. The commercial manufacture, use, offer for sale, sale and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894, which will actively induce and/or contribute to infringement of the '111 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 264. Unless Mylan is enjoined from actively inducing and contributing to the infringement of the '111 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 265. On information and belief, despite having actual notice of the '111 Patent, Mylan continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '111 Patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

#### **Count XIII**

(Infringement of the '162 Patent Under 35 U.S.C. § 271(e)(2) by Teva's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 266. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 267. Teva submitted ANDA No. 203880 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Teva has committed an act of infringement of the '162 Patent under 35 U.S.C. § 271(e)(2)(A).

- 268. On information and belief, Teva became aware of the '162 Patent no later than the date on which that patent was listed in the Orange Book.
- 269. On information and belief, Teva knows or should know that the commercial offer for sale and sale of Teva's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880, will constitute an act of induced infringement and will contribute to actual infringement of the '162 Patent.
- 270. On information and belief, Teva knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will be especially made for or especially adapted for an infringement of the '162 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will actively contribute to the actual infringement of the '162 Patent.
- 271. The commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

#### **Count XIV**

(Declaratory Judgment of Infringement of the '162 Patent Under 35 U.S.C. § 271(b) and (c) by Teva's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 272. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 273. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

- 274. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
  - 275. Teva has actual knowledge of the '162 Patent.
- 276. On information and belief, Teva became aware of the '162 Patent no later than the date on which that patent was listed in the Orange Book.
- 277. On information and belief, Teva has acted with full knowledge of the '162 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '162 Patent.
- 278. The commercial manufacture, use, sale, offer for sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will induce the actual infringement of the '162 Patent.
- 279. On information and belief, Teva knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will actively induce the actual infringement of the '162 Patent.
- 280. On information and belief, Teva will encourage another's infringement of the '162 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880, which is covered by certain claims of the '162 Patent.
- 281. Teva's acts of infringement will be done with knowledge of the '162 Patent and with the intent to encourage infringement.

- 282. The foregoing actions by Teva will constitute active inducement of infringement of the '162 Patent.
- 283. On information and belief, Teva knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will be especially made or especially adapted for use in an infringement of the '162 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 284. The commercial manufacture, use, sale, offer for sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will contribute to the actual infringement of the '162 Patent.
- 285. On information and belief, Teva knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% described in ANDA No. 203880 will contribute to the actual infringement of the '162 Patent.
- 286. The foregoing actions by Teva will constitute contributory infringement of the '162 Patent.
- 287. On information and belief, Teva intends to, and will, actively induce and contribute to the infringement of the '162 Patent when ANDA No. 203880 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 288. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 by Teva will induce and/or contribute to the infringement of the '162 Patent.
- 289. The commercial manufacture, use, offer for sale, sale and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in

ANDA No. 203880, which will actively induce and/or contribute to infringement of the '162 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.

- 290. Unless Teva is enjoined from actively inducing and contributing to the infringement of the '162 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 291. On information and belief, despite having actual notice of the '162 Patent, Teva continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '162 Patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

### Count XV

(Infringement of the '162 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 292. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 293. Apotex submitted ANDA No. 207606 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Apotex has committed an act of infringement of the '162 Patent under 35 U.S.C. § 271(e)(2)(A).
- 294. On information and belief, Apotex became aware of the '162 Patent no later than the date on which that patent was listed in the Orange Book.
- 295. On information and belief, Apotex knows or should know that the commercial offer for sale and sale of Apotex's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product

described in ANDA No. 207606, will constitute an act of induced infringement and will contribute to actual infringement of the '162 Patent.

- 296. On information and belief, Apotex knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will be especially made for or especially adapted for an infringement of the '162 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will actively contribute to the actual infringement of the '162 Patent.
- 297. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

#### **Count XVI**

(Declaratory Judgment of Infringement of the '162 Patent Under 35 U.S.C. § 271(b) and (c) by Apotex's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 298. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 299. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 300. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
  - 301. Apotex has actual knowledge of the '162 Patent.

- 302. On information and belief, Apotex became aware of the '162 Patent no later than the date on which that patent was listed in the Orange Book.
- 303. On information and belief, Apotex has acted with full knowledge of the '162 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '162 Patent.
- 304. The commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will induce the actual infringement of the '162 Patent.
- 305. On information and belief, Apotex knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will actively induce the actual infringement of the '162 Patent.
- 306. On information and belief, Apotex will encourage another's infringement of the '162 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606, which is covered by certain claims of the '162 Patent.
- 307. Apotex's acts of infringement will be done with knowledge of the '162 Patent and with the intent to encourage infringement.
- 308. The foregoing actions by Apotex will constitute active inducement of infringement of the '162 Patent.
- 309. On information and belief, Apotex knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will

be especially made or especially adapted for use in an infringement of the '162 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

- 310. The commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will contribute to the actual infringement of the '162 Patent.
- 311. On information and belief, Apotex knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will contribute to the actual infringement of the '162 Patent.
- 312. The foregoing actions by Apotex will constitute contributory infringement of the '162 Patent.
- 313. On information and belief, Apotex intends to, and will, actively induce and contribute to the infringement of the '162 Patent when ANDA No. 207606 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 314. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 by Apotex will induce and/or contribute to the infringement of the '162 Patent.
- 315. The commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606, which will actively induce and/or contribute to infringement of the '162 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.

- 316. Unless Apotex is enjoined from actively inducing and contributing to the infringement of the '162 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 317. On information and belief, despite having actual notice of the '162 Patent, Apotex continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '162 Patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

#### **Count XVII**

(Infringement of the '162 Patent Under 35 U.S.C. § 271(e)(2) by Akorn's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 318. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 319. Akorn submitted ANDA No. 204561 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Akorn has committed an act of infringement of the '162 Patent under 35 U.S.C. § 271(e)(2)(A).
- 320. On information and belief, Akorn became aware of the '162 Patent no later than the date on which that patent was listed in the Orange Book.
- 321. On information and belief, Akorn knows or should know that the commercial offer for sale and sale of Akorn's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561, will constitute an act of induced infringement and will contribute to actual infringement of the '162 Patent.
- 322. On information and belief, Akorn knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will be

especially made for or especially adapted for an infringement of the '162 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will actively contribute to the actual infringement of the '162 Patent.

323. The commercial manufacture, use, offer for sale, sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

#### **Count XVIII**

(Declaratory Judgment of Infringement of the '162 Patent Under 35 U.S.C. § 271(b) and (c) by Akorn's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 324. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 325. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 326. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
  - 327. Akorn has actual knowledge of the '162 Patent.
- 328. On information and belief, Akorn became aware of the '162 Patent no later than the date on which that patent was listed in the Orange Book.
- 329. On information and belief, Akorn has acted with full knowledge of the '162 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '162 Patent.

- 330. The commercial manufacture, use, sale, offer for sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will induce the actual infringement of the '162 Patent.
- 331. On information and belief, Akorn knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will actively induce the actual infringement of the '162 Patent.
- 332. On information and belief, Akorn will encourage another's infringement of the '162 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561, which is covered by certain claims of the '162 Patent.
- 333. Akorn's acts of infringement will be done with knowledge of the '162 Patent and with the intent to encourage infringement.
- 334. The foregoing actions by Akorn will constitute active inducement of infringement of the '162 Patent.
- 335. On information and belief, Akorn knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will be especially made or especially adapted for use in an infringement of the '162 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 336. The commercial manufacture, use, sale, offer for sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will contribute to the actual infringement of the '162 Patent.

- 337. On information and belief, Akorn knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will contribute to the actual infringement of the '162 Patent.
- 338. The foregoing actions by Akorn will constitute contributory infringement of the '162 Patent.
- 339. On information and belief, Akorn intends to, and will, actively induce and contribute to the infringement of the '162 Patent when ANDA No. 204561 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 340. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 by Akorn will induce and/or contribute to the infringement of the '162 Patent.
- 341. The commercial manufacture, use, offer for sale, sale and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561, which will actively induce and/or contribute to infringement of the '162 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 342. Unless Akorn is enjoined from actively inducing and contributing to the infringement of the '162 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 343. On information and belief, despite having actual notice of the '162 Patent, Akorn continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to

infringement of the '162 Patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

#### **Count XIX**

(Infringement of the '162 Patent Under 35 U.S.C. § 271(e)(2) by Mylan's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 344. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 345. Mylan submitted ANDA No. 205894 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Mylan has committed an act of infringement of the '162 Patent under 35 U.S.C. § 271(e)(2)(A).
- 346. On information and belief, Mylan became aware of the '162 Patent no later than the date on which that patent was listed in the Orange Book.
- 347. On information and belief, Mylan knows or should know that the commercial offer for sale and sale of Mylan's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894, will constitute an act of induced infringement and will contribute to actual infringement of the '162 Patent.
- 348. On information and belief, Mylan knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will be especially made for or especially adapted for an infringement of the '162 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will actively contribute to the actual infringement of the '162 Patent.

349. The commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

#### **Count XX**

- (Declaratory Judgment of Infringement of the '162 Patent Under 35 U.S.C. § 271(b) and (c) by Mylan's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)
  - 350. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 351. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 352. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
  - 353. Mylan has actual knowledge of the '162 Patent.
- 354. On information and belief, Mylan became aware of the '162 Patent no later than the date on which that patent was listed in the Orange Book.
- 355. On information and belief, Mylan has acted with full knowledge of the '162 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '162 Patent.
- 356. The commercial manufacture, use, sale, offer for sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will induce the actual infringement of the '162 Patent.
- 357. On information and belief, Mylan knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine

Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will actively induce the actual infringement of the '162 Patent.

- 358. On information and belief, Mylan will encourage another's infringement of the '162 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894, which is covered by certain claims of the '162 Patent.
- 359. Mylan's acts of infringement will be done with knowledge of the '162 Patent and with the intent to encourage infringement.
- 360. The foregoing actions by Mylan will constitute active inducement of infringement of the '162 Patent.
- 361. On information and belief, Mylan knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will be especially made or especially adapted for use in an infringement of the '162 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 362. The commercial manufacture, use, sale, offer for sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will contribute to the actual infringement of the '162 Patent.
- 363. On information and belief, Mylan knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% described in ANDA No. 205894 will contribute to the actual infringement of the '162 Patent.
- 364. The foregoing actions by Mylan will constitute contributory infringement of the '162 Patent.

- 365. On information and belief, Mylan intends to, and will, actively induce and contribute to the infringement of the '162 Patent when ANDA No. 205894 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 366. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 by Mylan will induce and/or contribute to the infringement of the '162 Patent.
- 367. The commercial manufacture, use, offer for sale, sale and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894, which will actively induce and/or contribute to infringement of the '162 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 368. Unless Mylan is enjoined from actively inducing and contributing to the infringement of the '162 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 369. On information and belief, despite having actual notice of the '162 Patent, Mylan continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '162 Patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

#### Count XXI

(Infringement of the '556 Patent Under 35 U.S.C. § 271(e)(2) by Teva's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

370. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

- 371. Teva submitted ANDA No. 203880 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Teva has committed an act of infringement of the '556 Patent under 35 U.S.C. § 271(e)(2)(A).
- 372. The commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will constitute an act of direct infringement of the '556 Patent.
- 373. On information and belief, Teva became aware of the '556 Patent no later than the date on which that patent was listed in the Orange Book.
- 374. On information and belief, Teva knows or should know that the commercial offer for sale and sale of Teva's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880, will constitute an act of induced infringement and will contribute to actual infringement of the '556 Patent.
- 375. On information and belief, Teva knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will be especially made for or especially adapted for an infringement of the '556 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will actively contribute to the actual infringement of the '556 Patent.
- 376. The commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in

ANDA No. 203880 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

#### **Count XXII**

## (Declaratory Judgment of Infringement of the '556 Patent Under 35 U.S.C. § 271(a) by Teva)

- 377. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 378. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 379. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
- 380. The commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will constitute an act of direct infringement of one or more claims of the '556 Patent.
- 381. On information and belief, Teva will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product immediately and imminently upon approval of ANDA No. 203880.
  - 382. The foregoing actions by Teva will constitute infringement of the '556 Patent.
  - 383. Teva will commit those acts of infringement without license or authorization.
- 384. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 by Teva will infringe the '556 Patent.

385. Unless Teva is enjoined from infringing the '556 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

#### **Count XXIII**

- (Declaratory Judgment of Infringement of the '556 Patent Under 35 U.S.C. § 271(b) and (c) by Teva's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)
  - 386. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 387. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 388. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
  - 389. Teva has actual knowledge of the '556 Patent.
- 390. On information and belief, Teva became aware of the '556 Patent no later than the date on which that patent was listed in the Orange Book.
- 391. On information and belief, Teva has acted with full knowledge of the '556 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '556 Patent.
- 392. The commercial manufacture, use, sale, offer for sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will induce the actual infringement of the '556 Patent.
- 393. On information and belief, Teva knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will actively induce the actual infringement of the '556 Patent.

- 394. On information and belief, Teva will encourage another's infringement of the '556 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880, which is covered by certain claims of the '556 Patent.
- 395. Teva's acts of infringement will be done with knowledge of the '556 Patent and with the intent to encourage infringement.
- 396. The foregoing actions by Teva will constitute active inducement of infringement of the '556 Patent.
- 397. On information and belief, Teva knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will be especially made or especially adapted for use in an infringement of the '556 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 398. The commercial manufacture, use, sale, offer for sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will contribute to the actual infringement of the '556 Patent.
- 399. On information and belief, Teva knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will contribute to the actual infringement of the '556 Patent.
- 400. The foregoing actions by Teva will constitute contributory infringement of the '556 Patent.
- 401. On information and belief, Teva intends to, and will, actively induce and contribute to the infringement of the '556 Patent when ANDA No. 203880 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

- 402. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 by Teva will induce and/or contribute to the infringement of the '556 Patent.
- 403. The commercial manufacture, use, offer for sale, sale and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880, which will actively induce and/or contribute to infringement of the '556 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 404. Unless Teva is enjoined from actively inducing and contributing to the infringement of the '556 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 405. On information and belief, despite having actual notice of the '556 Patent, Teva continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '556 Patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

#### **Count XXIV**

# (Infringement of the '556 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 406. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 407. Apotex submitted ANDA No. 207606 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product

throughout the United States. By submitting this application, Apotex has committed an act of infringement of the '556 Patent under 35 U.S.C. § 271(e)(2)(A).

- 408. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will constitute an act of direct infringement of the '556 Patent.
- 409. On information and belief, Apotex became aware of the '556 Patent no later than the date on which that patent was listed in the Orange Book.
- 410. On information and belief, Apotex knows or should know that the commercial offer for sale and sale of Apotex's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606, will constitute an act of induced infringement and will contribute to actual infringement of the '556 Patent.
- 411. On information and belief, Apotex knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will be especially made for or especially adapted for an infringement of the '556 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will actively contribute to the actual infringement of the '556 Patent.
- 412. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

#### **Count XXV**

### (Declaratory Judgment of Infringement of the '556 Patent Under 35 U.S.C. § 271(a) by Apotex)

- 413. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 414. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 415. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
- 416. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will constitute an act of direct infringement of one or more claims of the '556 Patent.
- 417. On information and belief, Apotex will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 immediately and imminently upon approval of ANDA No. 207606.
  - 418. The foregoing actions by Apotex will constitute infringement of the '556 Patent.
  - 419. Apotex will commit those acts of infringement without license or authorization.
- 420. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 by Apotex will infringe the '556 Patent.

421. Unless Apotex is enjoined from infringing the '556 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

#### **Count XXVI**

- (Declaratory Judgment of Infringement of the '556 Patent Under 35 U.S.C. § 271(b) and (c) by Apotex's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)
  - 422. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 423. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 424. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
  - 425. Apotex has actual knowledge of the '556 Patent.
- 426. On information and belief, Apotex became aware of the '556 Patent no later than the date on which that patent was listed in the Orange Book.
- 427. On information and belief, Apotex has acted with full knowledge of the '556 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '556 Patent.
- 428. The commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will induce the actual infringement of the '556 Patent.
- 429. On information and belief, Apotex knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will actively induce the actual infringement of the '556 Patent.

- 430. On information and belief, Apotex will encourage another's infringement of the '556 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606, which is covered by certain claims of the '556 Patent.
- 431. Apotex's acts of infringement will be done with knowledge of the '556 Patent and with the intent to encourage infringement.
- 432. The foregoing actions by Apotex will constitute active inducement of infringement of the '556 Patent.
- 433. On information and belief, Apotex knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will be especially made or especially adapted for use in an infringement of the '556 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 434. The commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will contribute to the actual infringement of the '556 Patent.
- 435. On information and belief, Apotex knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% described in ANDA No. 207606 will contribute to the actual infringement of the '556 Patent.
- 436. The foregoing actions by Apotex will constitute contributory infringement of the '556 Patent.
- 437. On information and belief, Apotex intends to, and will, actively induce and contribute to the infringement of the '556 Patent when ANDA No. 207606 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

- 438. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 by Apotex will induce and/or contribute to the infringement of the '556 Patent.
- 439. The commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606, which will actively induce and/or contribute to infringement of the '556 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 440. Unless Apotex is enjoined from actively inducing and contributing to the infringement of the '556 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 441. On information and belief, despite having actual notice of the '556 Patent, Apotex continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '556 Patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

#### **Count XXVII**

### (Infringement of the '556 Patent Under 35 U.S.C. § 271(e)(2) by Akorn's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 442. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 443. Akorn submitted ANDA No. 204561 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product

throughout the United States. By submitting this application, Akorn has committed an act of infringement of the '556 Patent under 35 U.S.C. § 271(e)(2)(A).

- 444. The commercial manufacture, use, offer for sale, sale, and/or importation of Akorn's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will constitute an act of direct infringement of the '556 Patent.
- 445. On information and belief, Akorn became aware of the '556 Patent no later than the date on which that patent was listed in the Orange Book.
- 446. On information and belief, Akorn knows or should know that the commercial offer for sale and sale of Akorn's proposed Cyclosporine Ophthalmic Emulsion, 0.05% described in ANDA No. 204561, will constitute an act of induced infringement and will contribute to actual infringement of the '556 Patent.
- 447. On information and belief, Akorn knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will be especially made for or especially adapted for an infringement of the '556 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will actively contribute to the actual infringement of the '556 Patent.
- 448. The commercial manufacture, use, offer for sale, sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

#### **Count XXVIII**

### (Declaratory Judgment of Infringement of the '556 Patent Under 35 U.S.C. § 271(a) by Akorn)

- 449. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 450. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 451. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
- 452. The commercial manufacture, use, offer for sale, sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will constitute an act of direct infringement of one or more claims of the '556 Patent.
- 453. On information and belief, Akorn will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 immediately and imminently upon approval of ANDA No. 204561.
  - 454. The foregoing actions by Akorn will constitute infringement of the '556 Patent.
  - 455. Akorn will commit those acts of infringement without license or authorization.
- 456. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 by Akorn will infringe the '556 Patent.

457. Unless Akorn is enjoined from infringing the '556 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

#### **Count XXIX**

- (Declaratory Judgment of Infringement of the '556 Patent Under 35 U.S.C. § 271(b) and (c) by Akorn's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)
  - 458. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 459. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 460. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
  - 461. Akorn has actual knowledge of the '556 Patent.
- 462. On information and belief, Akorn became aware of the '556 Patent no later than the date on which that patent was listed in the Orange Book.
- 463. On information and belief, Akorn has acted with full knowledge of the '556 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '556 Patent.
- 464. The commercial manufacture, use, sale, offer for sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will induce the actual infringement of the '556 Patent.
- 465. On information and belief, Akorn knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will actively induce the actual infringement of the '556 Patent.

- 466. On information and belief, Akorn will encourage another's infringement of the '556 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561, which is covered by certain claims of the '556 Patent.
- 467. Akorn's acts of infringement will be done with knowledge of the '556 Patent and with the intent to encourage infringement.
- 468. The foregoing actions by Akorn will constitute active inducement of infringement of the '556 Patent.
- 469. On information and belief, Akorn knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will be especially made or especially adapted for use in an infringement of the '556 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 470. The commercial manufacture, use, sale, offer for sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will contribute to the actual infringement of the '556 Patent.
- 471. On information and belief, Akorn knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will contribute to the actual infringement of the '556 Patent.
- 472. The foregoing actions by Akorn will constitute contributory infringement of the '556 Patent.

- 473. On information and belief, Akorn intends to, and will, actively induce and contribute to the infringement of the '556 Patent when ANDA No. 204561 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 474. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 by Akorn will induce and/or contribute to the infringement of the '556 Patent.
- 475. The commercial manufacture, use, offer for sale, sale and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561, which will actively induce and/or contribute to infringement of the '556 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 476. Unless Akorn is enjoined from actively inducing and contributing to the infringement of the '556 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 477. On information and belief, despite having actual notice of the '556 Patent, Akorn continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '556 Patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

#### Count XXX

(Infringement of the '556 Patent Under 35 U.S.C. § 271(e)(2) by Mylan's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

478. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

- 479. Mylan submitted ANDA No. 205894 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Mylan has committed an act of infringement of the '556 Patent under 35 U.S.C. § 271(e)(2)(A).
- 480. The commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will constitute an act of direct infringement of the '556 Patent.
- 481. On information and belief, Mylan became aware of the '556 Patent no later than the date on which that patent was listed in the Orange Book.
- 482. On information and belief, Mylan knows or should know that the commercial offer for sale and sale of Mylan's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894, will constitute an act of induced infringement and will contribute to actual infringement of the '556 Patent.
- 483. On information and belief, Mylan knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will be especially made for or especially adapted for an infringement of the '556 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will actively contribute to the actual infringement of the '556 Patent.
- 484. The commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in

ANDA No. 205894 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

#### **Count XXXI**

### (Declaratory Judgment of Infringement of the '556 Patent Under 35 U.S.C. § 271(a) by Mylan)

- 485. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 486. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 487. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
- 488. The commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will constitute an act of direct infringement of one or more claims of the '556 Patent.
- 489. On information and belief, Mylan will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 immediately and imminently upon approval of ANDA No. 205894.
  - 490. The foregoing actions by Mylan will constitute infringement of the '556 Patent.
  - 491. Mylan will commit those acts of infringement without license or authorization.
- 492. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed generic

Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 by Mylan will infringe the '556 Patent.

493. Unless Mylan is enjoined from infringing the '556 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

#### **Count XXXII**

- (Declaratory Judgment of Infringement of the '556 Patent Under 35 U.S.C. § 271(b) and (c) by Mylan's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)
  - 494. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 495. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 496. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
  - 497. Mylan has actual knowledge of the '556 Patent.
- 498. On information and belief, Mylan became aware of the '556 Patent no later than the date on which that patent was listed in the Orange Book.
- 499. On information and belief, Mylan has acted with full knowledge of the '556 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '556 Patent.
- 500. The commercial manufacture, use, sale, offer for sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will induce the actual infringement of the '556 Patent.
- 501. On information and belief, Mylan knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine

Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will actively induce the actual infringement of the '556 Patent.

- 502. On information and belief, Mylan will encourage another's infringement of the '556 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894, which is covered by certain claims of the '556 Patent.
- 503. Mylan's acts of infringement will be done with knowledge of the '556 Patent and with the intent to encourage infringement.
- 504. The foregoing actions by Mylan will constitute active inducement of infringement of the '556 Patent.
- 505. On information and belief, Mylan knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will be especially made or especially adapted for use in an infringement of the '556 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 506. The commercial manufacture, use, sale, offer for sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will contribute to the actual infringement of the '556 Patent.
- 507. On information and belief, Mylan knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will contribute to the actual infringement of the '556 Patent.
- 508. The foregoing actions by Mylan will constitute contributory infringement of the '556 Patent.

- 509. On information and belief, Mylan intends to, and will, actively induce and contribute to the infringement of the '556 Patent when ANDA No. 205894 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 510. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 by Mylan will induce and/or contribute to the infringement of the '556 Patent.
- 511. The commercial manufacture, use, offer for sale, sale and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894, which will actively induce and/or contribute to infringement of the '556 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 512. Unless Mylan is enjoined from actively inducing and contributing to the infringement of the '556 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 513. On information and belief, despite having actual notice of the '556 Patent, Mylan continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '556 Patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

#### **Count XXXIII**

(Infringement of the '048 Patent Under 35 U.S.C. § 271(e)(2) by Teva's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

514. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

- 515. Teva submitted ANDA No. 203880 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Teva has committed an act of infringement of the '048 Patent under 35 U.S.C. § 271(e)(2)(A).
- 516. On information and belief, Teva became aware of the '048 Patent no later than the date on which that patent was listed in the Orange Book.
- 517. On information and belief, Teva knows or should know that the commercial offer for sale and sale of Teva's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880, will constitute an act of induced infringement and will contribute to actual infringement of the '048 Patent.
- 518. On information and belief, Teva knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will be especially made for or especially adapted for an infringement of the '048 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will actively contribute to the actual infringement of the '048 Patent.
- 519. The commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

### **Count XXXIV**

- (Declaratory Judgment of Infringement of the '048 Patent Under 35 U.S.C. § 271(b) and (c) by Teva's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)
  - 520. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 521. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 522. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
  - 523. Teva has actual knowledge of the '048 Patent.
- 524. On information and belief, Teva became aware of the '048 Patent no later than the date on which that patent was listed in the Orange Book.
- 525. On information and belief, Teva has acted with full knowledge of the '048 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '048 Patent.
- 526. The commercial manufacture, use, sale, offer for sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will induce the actual infringement of the '048 Patent.
- 527. On information and belief, Teva knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will actively induce the actual infringement of the '048 Patent.
- 528. On information and belief, Teva will encourage another's infringement of the '048 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or

importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880, which is covered by certain claims of the '048 Patent.

- 529. Teva's acts of infringement will be done with knowledge of the '048 Patent and with the intent to encourage infringement.
- 530. The foregoing actions by Teva will constitute active inducement of infringement of the '048 Patent.
- 531. On information and belief, Teva knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will be especially made or especially adapted for use in an infringement of the '048 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 532. The commercial manufacture, use, sale, offer for sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will contribute to the actual infringement of the '048 Patent.
- 533. On information and belief, Teva knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will contribute to the actual infringement of the '048 Patent.
- 534. The foregoing actions by Teva will constitute contributory infringement of the '048 Patent.
- 535. On information and belief, Teva intends to, and will, actively induce and contribute to the infringement of the '048 Patent when ANDA No. 203880 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 536. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed generic

Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 by Teva will induce and/or contribute to the infringement of the '048 Patent.

- 537. The commercial manufacture, use, offer for sale, sale and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880, which will actively induce and/or contribute to infringement of the '048 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 538. Unless Teva is enjoined from actively inducing and contributing to the infringement of the '048 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 539. On information and belief, despite having actual notice of the '048 Patent, Teva continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '048 Patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

#### **Count XXXV**

## (Infringement of the '048 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 540. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 541. Apotex submitted ANDA No. 207606 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Apotex has committed an act of infringement of the '048 Patent under 35 U.S.C. § 271(e)(2)(A).

- 542. On information and belief, Apotex became aware of the '048 Patent no later than the date on which that patent was listed in the Orange Book.
- 543. On information and belief, Apotex knows or should know that the commercial offer for sale and sale of Apotex's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606, will constitute an act of induced infringement and will contribute to actual infringement of the '048 Patent.
- 544. On information and belief, Apotex knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will be especially made for or especially adapted for an infringement of the '048 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will actively contribute to the actual infringement of the '048 Patent.
- 545. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

#### **Count XXXVI**

(Declaratory Judgment of Infringement of the '048 Patent Under 35 U.S.C. § 271(b) and (c) by Apotex's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 546. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 547. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

- 548. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
  - 549. Apotex has actual knowledge of the '048 Patent.
- 550. On information and belief, Apotex became aware of the '048 Patent no later than the date on which that patent was listed in the Orange Book.
- 551. On information and belief, Apotex has acted with full knowledge of the '048 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '048 Patent.
- 552. The commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will induce the actual infringement of the '048 Patent.
- 553. On information and belief, Apotex knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will actively induce the actual infringement of the '048 Patent.
- 554. On information and belief, Apotex will encourage another's infringement of the '048 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606, which is covered by certain claims of the '048 Patent.
- 555. Apotex's acts of infringement will be done with knowledge of the '048 Patent and with the intent to encourage infringement.

- 556. The foregoing actions by Apotex will constitute active inducement of infringement of the '048 Patent.
- 557. On information and belief, Apotex knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will be especially made or especially adapted for use in an infringement of the '048 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 558. The commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will contribute to the actual infringement of the '048 Patent.
- 559. On information and belief, Apotex knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will contribute to the actual infringement of the '048 Patent.
- 560. The foregoing actions by Apotex will constitute contributory infringement of the '048 Patent.
- 561. On information and belief, Apotex intends to, and will, actively induce and contribute to the infringement of the '048 Patent when ANDA No. 207606 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 562. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 by Apotex will induce and/or contribute to the infringement of the '048 Patent.

- 563. The commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606, which will actively induce and/or contribute to infringement of the '048 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 564. Unless Apotex is enjoined from actively inducing and contributing to the infringement of the '048 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 565. On information and belief, despite having actual notice of the '048 Patent, Apotex continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '048 Patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

### **Count XXXVII**

## (Infringement of the '048 Patent Under 35 U.S.C. § 271(e)(2) by Akorn's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 566. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 567. Akorn submitted ANDA No. 204561 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Akorn has committed an act of infringement of the '048 Patent under 35 U.S.C. § 271(e)(2)(A).
- 568. On information and belief, Akorn became aware of the '048 Patent no later than the date on which that patent was listed in the Orange Book.

- 569. On information and belief, Akorn knows or should know that the commercial offer for sale and sale of Akorn's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561, will constitute an act of induced infringement and will contribute to actual infringement of the '048 Patent.
- 570. On information and belief, Akorn knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will be especially made for or especially adapted for an infringement of the '048 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will actively contribute to the actual infringement of the '048 Patent.
- 571. The commercial manufacture, use, offer for sale, sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

### **Count XXXVIII**

(Declaratory Judgment of Infringement of the '048 Patent Under 35 U.S.C. § 271(b) and (c) by Akorn's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 572. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 573. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 574. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

- 575. Akorn has actual knowledge of the '048 Patent.
- 576. On information and belief, Akorn became aware of the '048 Patent no later than the date on which that patent was listed in the Orange Book.
- 577. On information and belief, Akorn has acted with full knowledge of the '048 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '048 Patent.
- 578. The commercial manufacture, use, sale, offer for sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will induce the actual infringement of the '048 Patent.
- 579. On information and belief, Akorn knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will actively induce the actual infringement of the '048 Patent.
- 580. On information and belief, Akorn will encourage another's infringement of the '048 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561, which is covered by certain claims of the '048 Patent.
- 581. Akorn's acts of infringement will be done with knowledge of the '048 Patent and with the intent to encourage infringement.
- 582. The foregoing actions by Akorn will constitute active inducement of infringement of the '048 Patent.
- 583. On information and belief, Akorn knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will be

especially made or especially adapted for use in an infringement of the '048 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

- 584. The commercial manufacture, use, sale, offer for sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will contribute to the actual infringement of the '048 Patent.
- 585. On information and belief, Akorn knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will contribute to the actual infringement of the '048 Patent.
- 586. The foregoing actions by Akorn will constitute contributory infringement of the '048 Patent.
- 587. On information and belief, Akorn intends to, and will, actively induce and contribute to the infringement of the '048 Patent when ANDA No. 204561 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 588. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 by Akorn will induce and/or contribute to the infringement of the '048 Patent.
- 589. The commercial manufacture, use, offer for sale, sale and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561, which will actively induce and/or contribute to infringement of the '048 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.

- 590. Unless Akorn is enjoined from actively inducing and contributing to the infringement of the '048 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 591. On information and belief, despite having actual notice of the '048 Patent, Akorn continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '048 Patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

### **Count XXXIX**

(Infringement of the '048 Patent Under 35 U.S.C. § 271(e)(2) by Mylan's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 592. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 593. Mylan submitted ANDA No. 205894 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Mylan has committed an act of infringement of the '048 Patent under 35 U.S.C. § 271(e)(2)(A).
- 594. On information and belief, Mylan became aware of the '048 Patent no later than the date on which that patent was listed in the Orange Book.
- 595. On information and belief, Mylan knows or should know that the commercial offer for sale and sale of Mylan's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894, will constitute an act of induced infringement and will contribute to actual infringement of the '048 Patent.
- 596. On information and belief, Mylan knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will be

especially made for or especially adapted for an infringement of the '048 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will actively contribute to the actual infringement of the '048 Patent.

597. The commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

#### **Count XL**

(Declaratory Judgment of Infringement of the '048 Patent Under 35 U.S.C. § 271(b) and (c) by Mylan's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 598. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 599. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 600. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
  - 601. Mylan has actual knowledge of the '048 Patent.
- 602. On information and belief, Mylan became aware of the '048 Patent no later than the date on which that patent was listed in the Orange Book.
- 603. On information and belief, Mylan has acted with full knowledge of the '048 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '048 Patent.

- 604. The commercial manufacture, use, sale, offer for sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will induce the actual infringement of the '048 Patent.
- 605. On information and belief, Mylan knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will actively induce the actual infringement of the '048 Patent.
- 606. On information and belief, Mylan will encourage another's infringement of the '048 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894, which is covered by certain claims of the '048 Patent.
- 607. Mylan's acts of infringement will be done with knowledge of the '048 Patent and with the intent to encourage infringement.
- 608. The foregoing actions by Mylan will constitute active inducement of infringement of the '048 Patent.
- 609. On information and belief, Mylan knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will be especially made or especially adapted for use in an infringement of the '048 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 610. The commercial manufacture, use, sale, offer for sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will contribute to the actual infringement of the '048 Patent.

- 611. On information and belief, Mylan knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will contribute to the actual infringement of the '048 Patent.
- 612. The foregoing actions by Mylan will constitute contributory infringement of the '048 Patent.
- 613. On information and belief, Mylan intends to, and will, actively induce and contribute to the infringement of the '048 Patent when ANDA No. 205894 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 614. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 by Mylan will induce and/or contribute to the infringement of the '048 Patent.
- 615. The commercial manufacture, use, offer for sale, sale and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894, which will actively induce and/or contribute to infringement of the '048 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 616. Unless Mylan is enjoined from actively inducing and contributing to the infringement of the '048 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 617. On information and belief, despite having actual notice of the '048 Patent, Mylan continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to

infringement of the '048 Patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

#### **Count XLI**

(Infringement of the '930 Patent Under 35 U.S.C. § 271(e)(2) by Teva's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 618. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 619. Teva submitted ANDA No. 203880 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Teva has committed an act of infringement of the '930 Patent under 35 U.S.C. § 271(e)(2)(A).
- 620. The commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will constitute an act of direct infringement of the '930 Patent.
- 621. On information and belief, Teva became aware of the '930 Patent no later than the date on which that patent was listed in the Orange Book.
- 622. On information and belief, Teva knows or should know that the commercial offer for sale and sale of Teva's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880, will constitute an act of induced infringement and will contribute to actual infringement of the '930 Patent.
- 623. On information and belief, Teva knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will be especially made for or especially adapted for an infringement of the '930 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its

commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will actively contribute to the actual infringement of the '930 Patent.

624. The commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

#### **Count XLII**

# (Declaratory Judgment of Infringement of the '930 Patent Under 35 U.S.C. § 271(a) by Teva)

- 625. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 626. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 627. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
- 628. The commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will constitute an act of direct infringement of one or more claims of the '930 Patent.
- 629. On information and belief, Teva will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 immediately and imminently upon approval of ANDA No. 203880.

- 630. The foregoing actions by Teva will constitute infringement of the '930 Patent.
- 631. Teva will commit those acts of infringement without license or authorization.
- 632. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 by Teva will infringe the '930 Patent.
- 633. Unless Teva is enjoined from infringing the '930 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

#### **Count XLIII**

(Declaratory Judgment of Infringement of the '930 Patent Under 35 U.S.C. § 271(b) and (c) by Teva's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 634. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 635. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 636. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
  - 637. Teva has actual knowledge of the '930 Patent.
- 638. On information and belief, Teva became aware of the '930 Patent no later than the date on which that patent was listed in the Orange Book.
- 639. On information and belief, Teva has acted with full knowledge of the '930 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '930 Patent.

- 640. The commercial manufacture, use, sale, offer for sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will induce the actual infringement of the '930 Patent.
- 641. On information and belief, Teva knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will actively induce the actual infringement of the '930 Patent.
- 642. On information and belief, Teva will encourage another's infringement of the '930 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880, which is covered by certain claims of the '930 Patent.
- 643. Teva's acts of infringement will be done with knowledge of the '930 Patent and with the intent to encourage infringement.
- 644. The foregoing actions by Teva will constitute active inducement of infringement of the '930 Patent.
- 645. On information and belief, Teva knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will be especially made or especially adapted for use in an infringement of the '930 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 646. The commercial manufacture, use, sale, offer for sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880 will contribute to the actual infringement of the '930 Patent.

- 647. On information and belief, Teva knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% described in ANDA No. 203880 will contribute to the actual infringement of the '930 Patent.
- 648. The foregoing actions by Teva will constitute contributory infringement of the '930 Patent.
- 649. On information and belief, Teva intends to, and will, actively induce and contribute to the infringement of the '930 Patent when ANDA No. 203880 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 650. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% described in ANDA No. 203880 product by Teva will induce and/or contribute to the infringement of the '930 Patent.
- 651. The commercial manufacture, use, offer for sale, sale and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880, which will actively induce and/or contribute to infringement of the '930 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 652. Unless Teva is enjoined from actively inducing and contributing to the infringement of the '930 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 653. On information and belief, despite having actual notice of the '930 Patent, Teva continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to

infringement of the '930 Patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

#### **Count XLIV**

# (Infringement of the '930 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 654. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 655. Apotex submitted ANDA No. 207606 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Apotex has committed an act of infringement of the '930 Patent under 35 U.S.C. § 271(e)(2)(A).
- 656. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will constitute an act of direct infringement of the '930 Patent.
- 657. On information and belief, Apotex became aware of the '930 Patent no later than the date on which that patent was listed in the Orange Book.
- 658. On information and belief, Akorn knows or should know that the commercial offer for sale and sale of Apotex's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606, will constitute an act of induced infringement and will contribute to actual infringement of the '930 Patent.
- 659. On information and belief, Apotex knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will be especially made for or especially adapted for an infringement of the '930 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its

commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will actively contribute to the actual infringement of the '930 Patent.

660. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

#### **Count XLV**

# (Declaratory Judgment of Infringement of the '930 Patent Under 35 U.S.C. § 271(a) by Apotex)

- 661. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 662. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 663. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
- 664. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will constitute an act of direct infringement of one or more claims of the '930 Patent.
- 665. On information and belief, Apotex will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 immediately and imminently upon approval of ANDA No. 207606.

- 666. The foregoing actions by Apotex will constitute infringement of the '930 Patent.
- 667. Apotex will commit those acts of infringement without license or authorization.
- 668. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 by Apotex will infringe the '930 Patent.
- 669. Unless Apotex is enjoined from infringing the '930 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

#### **Count XLVI**

(Declaratory Judgment of Infringement of the '930 Patent Under 35 U.S.C. § 271(b) and (c) by Apotex's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 670. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 671. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 672. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
  - 673. Apotex has actual knowledge of the '930 Patent.
- 674. On information and belief, Apotex became aware of the '930 Patent no later than the date on which that patent was listed in the Orange Book.
- 675. On information and belief, Apotex has acted with full knowledge of the '930 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '930 Patent.

- 676. The commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will induce the actual infringement of the '930 Patent.
- 677. On information and belief, Apotex knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will actively induce the actual infringement of the '930 Patent.
- 678. On information and belief, Apotex will encourage another's infringement of the '930 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606, which is covered by certain claims of the '930 Patent.
- 679. Apotex's acts of infringement will be done with knowledge of the '930 Patent and with the intent to encourage infringement.
- 680. The foregoing actions by Apotex will constitute active inducement of infringement of the '930 Patent.
- 681. On information and belief, Apotex knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will be especially made or especially adapted for use in an infringement of the '930 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 682. The commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will contribute to the actual infringement of the '930 Patent.

- 683. On information and belief, Apotex knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 will contribute to the actual infringement of the '930 Patent.
- 684. The foregoing actions by Apotex will constitute contributory infringement of the '930 Patent.
- 685. On information and belief, Apotex intends to, and will, actively induce and contribute to the infringement of the '930 Patent when ANDA No. 207606 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 686. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606 by Apotex will induce and/or contribute to the infringement of the '930 Patent.
- 687. The commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606, which will actively induce and/or contribute to infringement of the '930 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 688. Unless Apotex is enjoined from actively inducing and contributing to the infringement of the '930 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 689. On information and belief, despite having actual notice of the '930 Patent, Apotex continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to

infringement of the '930 Patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

### **Count XLVII**

(Infringement of the '930 Patent Under 35 U.S.C. § 271(e)(2) by Akorn's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 690. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 691. Akorn submitted ANDA No. 204561 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Akorn has committed an act of infringement of the '930 Patent under 35 U.S.C. § 271(e)(2)(A).
- 692. The commercial manufacture, use, offer for sale, sale, and/or importation of Akorn's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will constitute an act of direct infringement of the '930 Patent.
- 693. On information and belief, Akorn became aware of the '930 Patent no later than the date on which that patent was listed in the Orange Book.
- 694. On information and belief, Akorn knows or should know that the commercial offer for sale and sale of Akorn's proposed Cyclosporine Ophthalmic Emulsion, 0.05% described in ANDA No. 204561, will constitute an act of induced infringement and will contribute to actual infringement of the '930 Patent.
- 695. On information and belief, Akorn knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will be especially made for or especially adapted for an infringement of the '930 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its

commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will actively contribute to the actual infringement of the '930 Patent.

696. The commercial manufacture, use, offer for sale, sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

#### **Count XLVIII**

# (Declaratory Judgment of Infringement of the '930 Patent Under 35 U.S.C. § 271(a) by Akorn)

- 697. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 698. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 699. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
- 700. The commercial manufacture, use, offer for sale, sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will constitute an act of direct infringement of one or more claims of the '930 Patent.
- 701. On information and belief, Akorn will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 immediately and imminently upon approval of ANDA No. 204561.

- 702. The foregoing actions by Akorn will constitute infringement of the '930 Patent.
- 703. Akorn will commit those acts of infringement without license or authorization.
- 704. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 by Akorn will infringe the '930 Patent.
- 705. Unless Akorn is enjoined from infringing the '930 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

## **Count XLIX**

(Declaratory Judgment of Infringement of the '930 Patent Under 35 U.S.C. § 271(b) and (c) by Akorn's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 706. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 707. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 708. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
  - 709. Akorn has actual knowledge of the '930 Patent.
- 710. On information and belief, Akorn became aware of the '930 Patent no later than the date on which that patent was listed in the Orange Book.
- 711. On information and belief, Akorn has acted with full knowledge of the '930 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '930 Patent.

- 712. The commercial manufacture, use, sale, offer for sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will induce the actual infringement of the '930 Patent.
- 713. On information and belief, Akorn knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will actively induce the actual infringement of the '930 Patent.
- 714. On information and belief, Akorn will encourage another's infringement of the '930 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561, which is covered by certain claims of the '930 Patent.
- 715. Akorn's acts of infringement will be done with knowledge of the '930 Patent and with the intent to encourage infringement.
- 716. The foregoing actions by Akorn will constitute active inducement of infringement of the '930 Patent.
- 717. On information and belief, Akorn knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will be especially made or especially adapted for use in an infringement of the '930 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 718. The commercial manufacture, use, sale, offer for sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will contribute to the actual infringement of the '930 Patent.

- 719. On information and belief, Akorn knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 will contribute to the actual infringement of the '930 Patent.
- 720. The foregoing actions by Akorn will constitute contributory infringement of the '930 Patent.
- 721. On information and belief, Akorn intends to, and will, actively induce and contribute to the infringement of the '930 Patent when ANDA No. 204561 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 722. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561 by Akorn will induce and/or contribute to the infringement of the '930 Patent.
- 723. The commercial manufacture, use, offer for sale, sale and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561, which will actively induce and/or contribute to infringement of the '930 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 724. Unless Akorn is enjoined from actively inducing and contributing to the infringement of the '930 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 725. On information and belief, despite having actual notice of the '930 Patent, Akorn continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to

infringement of the '930 Patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

## Count L

(Infringement of the '930 Patent Under 35 U.S.C. § 271(e)(2) by Mylan's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 726. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 727. Mylan submitted ANDA No. 205894 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Mylan has committed an act of infringement of the '930 Patent under 35 U.S.C. § 271(e)(2)(A).
- 728. The commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will constitute an act of direct infringement of the '930 Patent.
- 729. On information and belief, Mylan became aware of the '930 Patent no later than the date on which that patent was listed in the Orange Book.
- 730. On information and belief, Mylan knows or should know that the commercial offer for sale and sale of Mylan's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894, will constitute an act of induced infringement and will contribute to actual infringement of the '930 Patent.
- 731. On information and belief, Mylan knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will be especially made for or especially adapted for an infringement of the '930 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its

commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will actively contribute to the actual infringement of the '930 Patent.

732. The commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

#### **Count LI**

# (Declaratory Judgment of Infringement of the '930 Patent Under 35 U.S.C. § 271(a) by Mylan)

- 733. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 734. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 735. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
- 736. The commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will constitute an act of direct infringement of one or more claims of the '930 Patent.
- 737. On information and belief, Mylan will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed generic Cyclosporine

  Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 immediately and imminently upon approval of ANDA No. 205894.

- 738. The foregoing actions by Mylan will constitute infringement of the '930 Patent.
- 739. Mylan will commit those acts of infringement without license or authorization.
- 740. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 by Mylan will infringe the '930 Patent.
- 741. Unless Mylan is enjoined from infringing the '930 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

#### **Count LII**

(Declaratory Judgment of Infringement of the '930 Patent Under 35 U.S.C. § 271(b) and (c) by Mylan's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

- 742. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.
- 743. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 744. There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.
  - 745. Mylan has actual knowledge of the '930 Patent.
- 746. On information and belief, Mylan became aware of the '930 Patent no later than the date on which that patent was listed in the Orange Book.
- 747. On information and belief, Mylan has acted with full knowledge of the '930 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '930 Patent.

- 748. The commercial manufacture, use, sale, offer for sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will induce the actual infringement of the '930 Patent.
- 749. On information and belief, Mylan knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will actively induce the actual infringement of the '930 Patent.
- 750. On information and belief, Mylan will encourage another's infringement of the '930 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894, which is covered by certain claims of the '930 Patent.
- 751. Mylan's acts of infringement will be done with knowledge of the '930 Patent and with the intent to encourage infringement.
- 752. The foregoing actions by Mylan will constitute active inducement of infringement of the '930 Patent.
- 753. On information and belief, Mylan knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will be especially made or especially adapted for use in an infringement of the '930 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 754. The commercial manufacture, use, sale, offer for sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will contribute to the actual infringement of the '930 Patent.

- 755. On information and belief, Mylan knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 will contribute to the actual infringement of the '930 Patent.
- 756. The foregoing actions by Mylan will constitute contributory infringement of the '930 Patent.
- 757. On information and belief, Mylan intends to, and will, actively induce and contribute to the infringement of the '930 Patent when ANDA No. 205894 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.
- 758. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894 by Mylan will induce and/or contribute to the infringement of the '930 Patent.
- 759. The commercial manufacture, use, offer for sale, sale and/or importation of Mylan's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894, which will actively induce and/or contribute to infringement of the '930 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.
- 760. Unless Mylan is enjoined from actively inducing and contributing to the infringement of the '930 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.
- 761. On information and belief, despite having actual notice of the '930 Patent, Mylan continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to

infringement of the '930 Patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

### **Jury Trial Demand**

Pursuant to Federal Rule of Civil Procedure 38(b), Allergan hereby demands a trial by jury of all issues so triable.

## **Prayer for Relief**

Allergan respectfully prays for the following relief:

- 1. A finding that the '111, '162, '556, '048, and '930 Patents are valid and enforceable;
- 2. That a judgment be entered that Teva has infringed the '111, '162, '556, '048, and '930 Patents under 35 U.S.C. § 271(e)(2)(A) by submitting an ANDA under Section 505(j) of the FDCA;
- 3. That a declaration be issued under 28 U.S.C. § 2201 that if Teva, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf engage in the commercial manufacture, use, offer for sale, sale and/or importation of Teva's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880, it will constitute an act of infringement of the '111, '556, and '930 Patents under 35 U.S.C. § 271(a), (b), and (c);
- 4. That a declaration be issued under 28 U.S.C. § 2201 that if Teva, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf engage in the commercial manufacture, use, offer for sale, sale and/or importation of Teva's

proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 203880, it will constitute an act of infringement of the '162 and '048 Patents under 35 U.S.C. § 271(b) and (c);

- 5. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Teva's ANDA shall be a date which is not earlier than the latest expiration date of the '111, '162, '556, '048, and '930 Patents, including any extensions or periods of exclusivity;
- 6. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Teva, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '111, '162, '556, '048, and '930 Patents;
- 7. If Teva attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Teva's generic product disclosed in its ANDA prior to the expiration of the '111, '162, '556, '048, and '930 Patents, including any extensions or periods of exclusivity, a preliminary injunction be entered enjoining such conduct;
- 8. If Teva attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Teva's generic product disclosed in its ANDA prior to the expiration of the '111, '162, '556, '048, and '930 Patents, including any extensions or periods of exclusivity, judgment awarding Allergan damages resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

- 9. That a judgment be entered that Apotex has infringed the '111, '162, '556, '048, and '930 Patents under 35 U.S.C. § 271(e)(2)(A) by submitting an ANDA under Section 505(j) of the FDCA;
- 10. That a declaration be issued under 28 U.S.C. § 2201 that if Apotex, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf engage in the commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606, it will constitute an act of infringement of the '111, '556, and '930 Patents under 35 U.S.C. § 271(a), (b), and (c);
- 11. That a declaration be issued under 28 U.S.C. § 2201 that if Apotex, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf engage in the commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 207606, it will constitute an act of infringement of the '162 and '048 Patents under 35 U.S.C. § 271(b) and (c);
- 12. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Apotex's ANDA shall be a date which is not earlier than the latest expiration date of the '111, '162, '556, '048, and '930 Patents, including any extensions or periods of exclusivity;
- 13. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Apotex, its officers, agents, servants, employees, licensees, representatives, and

attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '111, '162, '556, '048, and '930 Patents;

- 14. If Apotex attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Apotex's generic product disclosed in its ANDA prior to the expiration of the '111, '162, '556, '048, and '930 Patents, including any extensions or periods of exclusivity, a preliminary injunction be entered enjoining such conduct;
- 15. If Apotex attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Apotex's generic product disclosed in its ANDA prior to the expiration of the '111, '162, '556, '048, and '930 Patents, including any extensions or periods of exclusivity, judgment awarding Allergan damages resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;
- 16. That a judgment be entered that Akorn has infringed the '111, '162, '556, '048, and '930 Patents under 35 U.S.C. § 271(e)(2)(A) by submitting an ANDA under Section 505(j) of the FDCA.
- 17. That a declaration be issued under 28 U.S.C. § 2201 that if Akorn, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf engage in the commercial manufacture, use, offer for sale, sale and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No.

204561, it will constitute an act of infringement of the '111, '556, and '930 Patents under 35 U.S.C. § 271(a), (b), and (c);

- 18. That a declaration be issued under 28 U.S.C. § 2201 that if Akorn, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf engage in the commercial manufacture, use, offer for sale, sale and/or importation of Akorn's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 204561, it will constitute an act of infringement of the '162 and '048 Patents under 35 U.S.C. § 271(b) and (c);
- 19. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Akorn's ANDA shall be a date which is not earlier than the latest expiration date of the '111, '162, '556, '048, and '930 Patents, including any extensions or periods of exclusivity;
- 20. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Akorn, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '111, '162, '556, '048, and '930 Patents;
- 21. If Akorn attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Akorn's generic product disclosed in its ANDA prior to the expiration of the '111, '162, '556, '048, and '930 Patents, including any extensions or periods of exclusivity, a preliminary injunction be entered enjoining such conduct;

- 22. If Akorn attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Akorn's generic product disclosed in its ANDA prior to the expiration of the '111, '162, '556, '048, and '930 Patents, including any extensions or periods of exclusivity, judgment awarding Allergan damages resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;
- 23. That a judgment be entered that Mylan has infringed the '111, '162, '556, '048, and '930 Patents under 35 U.S.C. § 271(e)(2)(A) by submitting an ANDA under Section 505(j) of the FDCA;
- 24. That a declaration be issued under 28 U.S.C. § 2201 that if Mylan, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf engage in the commercial manufacture, use, offer for sale, sale and/or importation of Mylan proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894, it will constitute an act of infringement of the '111, '556, and '930 Patents under 35 U.S.C. § 271(a), (b), and (c);
- 25. That a declaration be issued under 28 U.S.C. § 2201 that if Mylan, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf engage in the commercial manufacture, use, offer for sale, sale and/or importation of Mylan proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 205894, it will constitute an act of infringement of the '162 and '048 Patents under 35 U.S.C. § 271(b) and (c);

- 26. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Mylan's ANDA shall be a date which is not earlier than the latest expiration date of the '111, '162, '556, '048, and '930 Patents, including any extensions or periods of exclusivity;
- 27. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Mylan, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '111, '162, '556, '048, and '930 Patents;
- 28. If Mylan attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Mylan's generic product disclosed in its ANDA prior to the expiration of the '111, '162, '556, '048, and '930 Patents, including any extensions or periods of exclusivity, a preliminary injunction be entered enjoining such conduct;
- 29. If Mylan attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Mylan's generic product disclosed in its ANDA prior to the expiration of the '111, '162, '556, '048, and '930 Patents, including any extensions or periods of exclusivity, judgment awarding Allergan damages resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;
- 30. An accounting for any infringing sales not presented at trial and an award by the Court of any additional damages for any such infringing sales;

- 31. A finding that this action for infringement is an exceptional case under 35 U.S.C. § 285, and that Allergan be awarded reasonable attorneys' fees and costs; and
- 32. An award of any such other and further relief as the Court may deem just and proper.

Dated: August 24th, 2015 Respectfully submitted,

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**CERTIFICATE OF SERVICE** 

I hereby certify that a copy of the foregoing document was filed electronically in

compliance with Local Rule CV-5(a). Therefore, this document was served on all counsel who

are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A). Pursuant to Fed.

R. Civ. P. 5(d) and Local Rule CV-5(d) and (e), all other counsel of record not deemed to have

consented to electronic service were served with a true and correct copy of the foregoing by email

on this the 24th day of August, 2015.

/s/ Wesley Hill

Wesley Hill